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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,863	09/23/2003	Eric Schiller	P-6106	3151

26253 7590 12/14/2005

DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

HAN, MARK K

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,863

Applicant(s)

SCHILLER ET AL.

Examiner

Mark K. Han

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>see continuation</u> . | 6) <input type="checkbox"/> Other: ____ |

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Continuation of Attachment(s) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: 09 January 2004; 08 April 2004; 09 May 2005

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,331,538 to Higgins.

Higgins discloses a syringe having a barrel, plunger and having anti-reflux means 20/120/220/320. See Figures 1-9.

2. Claims 6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,899,881 to Grimard et al. (hereinafter "Grimard").

Grimard discloses a syringe assembly having a barrel 100, plunger 116, anti-reflux means 250, needle assembly 400 and flush solution. See Figures 1-12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins.

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Higgins discloses the claimed invention as shown above including a projection 220 on the distal surface of the stopper. Higgins also suggests using the combination of projections on the stopper and the distal wall of the syringe. See col. 3, lines 34-42. Higgins, however, does not disclose expressly an annular boss. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to replace the projections 20 with an annular boss because Applicant has not disclosed that an annular shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the projection of Higgins because both the projection and an annular boss would inhibit the stopper from making full contact with the distal wall of the syringe. Therefore, it would have been an obvious matter of design choice to modify Higgins to obtain the invention as specified in claims 2-5.

In reference to claim 8, Higgins meets the claimed limitations as disclosed above but fails to include the use of saline or a heparin lock. However, saline is a well-known flush agent for introduction into the body. One skilled in the art would have incorporated saline into the invention of Higgins based on this common knowledge in the art.

4. Claims 7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins in view of U.S. Patent No. 6,361,524 to Odell et al. (hereinafter "Odell").

Higgins discloses the claimed limitations as described above but does not disclose a tip cap. Odell teaches a cap for maintaining the sterility of the syringe contents before use and during transport. It would have been obvious to one of ordinary skill in the art to incorporate the

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cap into the invention of Higgins in order to maintain the sterility of the contents of the syringe prior to use thereby enhancing the safety of the patient from infection.

5. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,135,489 to Jepson et al. (hereinafter "Jepson") in view of Higgins.

Jepson discloses the claimed method of flushing a catheter. See col. 7, line 46 through col. 9, line 36. Jepson, however, does not disclose the syringe having anti-reflux means. Higgins discloses such a syringe as shown above. It would have been obvious to one of ordinary skill in the art to modify the invention of Jepson by including the syringe of Higgins in order to maintain a positive pressure in the IV line by preventing the stopper from drawing back after injection.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark K. Han
Patent Examiner
Art Unit 3767

mkh
December 12, 2005

KEVIN C. SIMONS
PRIMARY EXAMINER

